UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No. 1:24-cv-00070

BALDWIN PATTIE DRUG STORE, LLC, and MATTHEW D. KRAWCZAK, Hon.

Defendants.
_____/

COMPLAINT

The United States of America states the following as its Complaint against the Defendants:

I. INTRODUCTION

1. The opioid epidemic continues to harm Michiganders and their families, friends, and communities. Many communities remain plagued by the effects of this epidemic, marked by rising overdose deaths throughout the state.

2. Michigan's Lake County, in particular, is considered one of the most vulnerable communities in the state for adverse substance use outcomes.[1]

3. Because of the risk of addiction, misuse, and other diversion of controlled substances—and the inherent risk to patients and others who use these prescription drugs—Congress established the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971. Congress also tasked the U.S. Drug Enforcement Administration

[1] *See Data*, State of Michigan Opioid Resources, https://www.michigan.gov/opioids/category-data (last accessed Sept. 26, 2023).

("DEA") with enforcing laws regarding the prescribing and dispensing of controlled substances.

4. These laws include rules for when pharmacies may dispense controlled substances, as well as strict recordkeeping requirements for handling controlled substances.

5. When pharmacies and individuals violate these rules, the CSA imposes civil penalties and authorizes the United States to seek injunctive relief.

6. Baldwin Pattie Drug Store, LLC ("Pattie Drug"), a pharmacy located in Lake County, Michigan, and its owner and pharmacist-in-charge, Matthew D. Krawczak (collectively, the "Defendants"), violated the CSA. They did so by dispensing large quantities of opioids to patients despite knowing that these patients were seeking these pills due to their abuse potential. And they violated numerous recordkeeping requirements, resulting in large quantities of unaccounted-for drugs.

7. This is an action to recover civil penalties and obtain injunctive relief under the CSA against the Defendants for the following alleged violations.

II. JURISDICTION AND VENUE

8. The Court has jurisdiction pursuant to 21 U.S.C. §§ 842(c)(1), 843(f)(2), and 882(a), and 28 U.S.C. §§ 1331, 1345, and 1355(a).

9. Venue is appropriate in this District pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b)(1), 1391(b)(2), and 1395(a).

III. THE PARTIES

10. Plaintiff is the United States of America.

11. Defendant Pattie Drug is a pharmacy located at 868 Michigan Avenue, Baldwin, Michigan 49304. Pattie Drug is registered with the DEA as a retail pharmacy (Registration # FB2334352). Pattie Drug is organized in the State of Michigan as a domestic limited liability company (ID No. 801556554).

12. Defendant Matthew D. Krawczak is a resident of Lake County, Michigan. Krawczak is the owner of Pattie Drug and serves as its pharmacist in charge.

IV. LEGAL BACKGROUND

A. The Controlled Substances Act

13. The CSA creates a category of drugs, known as "controlled substances," that are subject to strict federal monitoring and regulation based on their potential for addiction and abuse. Controlled substances are categorized into five schedules based on several factors, including their abuse potential and the likelihood they will cause dependence if misused. A drug becomes a "controlled substance" when it is added to one of these schedules.

14. Schedule II controlled substances have "a high potential for abuse" and, if abused, "may lead to severe psychological or physical dependence." *See* 21 U.S.C. § 812(b)(2). Schedule II drugs include opioid-based painkillers such as oxycodone, hydrocodone (commonly sold under the brand names Norco and Vicodin), hydromorphone, morphine, fentanyl, and methadone. *See* 21 C.F.R. § 1308.12.

15. To prevent the diversion of controlled substances, the CSA regulates persons, companies, and other entities that manufacture, distribute, and dispense

controlled substances.

B. Registration

16. The CSA and its implementing regulations require those who handle controlled substances, other than the ultimate user, to obtain a controlled substance registration from DEA. 21 U.S.C. §§ 822, 823; 21 C.F.R § 1301. Persons or entities maintaining a controlled substance registration from DEA are referred to as "registrants."

17. In order for a pharmacy to dispense a controlled substance, that pharmacy must be registered with DEA.

C. Requirements for Dispensing a Prescription for a Controlled Substance

18. In order for a prescription for a controlled substance to be valid, the CSA requires that it be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 C.F.R. § 1306.04(a).

19. A pharmacist has a "corresponding responsibility" to fill only those prescriptions which are issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *Id.*

20. The CSA imposes a federal duty on a pharmacist to be vigilant in filling prescriptions in order to avoid filling those that are issued for a non-medical purpose. *United States v. Leal*, 75 F.3d 219, 227 (6th Cir. 1996), *abrogated on other grounds by United States v. Kennedy*, 107 F. App'x 518 (6th Cir. 2004).

21. The CSA further prohibits a pharmacy from dispensing such prescriptions. 21 U.S.C. §§ 829, 842(a)(1).

D. Recordkeeping and Reporting Requirements

22. Recordkeeping and making required reports to DEA are also critical to the closed system of distribution under the CSA and DEA's regulations.

23. As a general matter, DEA registrants must maintain a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant. 21 U.S.C. § 827(a); 21 C.F.R. § 1304.21(a).

24. The CSA and DEA's regulations contain a variety of specific recordkeeping and reporting requirements, including the following applicable to registered pharmacies:

a) *First*, a pharmacy that dispenses controlled substances must maintain a complete and accurate record of each controlled substance that it dispenses. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.22(c).

b) *Second*, a pharmacy must maintain records of receipt of controlled substances distributed to the pharmacy. 21 C.F.R. § 1305.17; 21 C.F.R. § 1304.22(c).

c) *Third*, a pharmacy that sells scheduled listed chemical products that contain ephedrine, pseudoephedrine, and phenylpropanolamine directly to customers must report annual certification to DEA that its employees have been trained on CSA requirements governing the sales of those products.

V. FACTS

A. Dispensing Violations

25. From 2018 through 2021, Defendants frequently purchased a particular brand of Hydrocodone-Acetaminophen 10mg – 325mg ("Hydrocodone") pills, a Schedule II controlled substance. This particular brand of Hydrocodone pills was yellow in color.

26. These yellow Hydrocodone pills—sometimes referred to as "yellow Norcos"—were commonly sought out by individuals for their purported abuse potential.

27. Defendants ordered and stocked these yellow Hydrocodone pills in order to maintain a competitive advantage over a neighboring pharmacy.

28. In violation of their corresponding responsibility under the CSA, Defendants then dispensed these yellow Hydrocodone pills to patients despite believing that these patients were abusing those drugs.

B. Recordkeeping and Reporting Violations

29. On December 6, 2022, DEA conducted an inspection of Pattie Drug pursuant to an administrative inspection warrant.

30. The inspection revealed a number of recordkeeping and reporting violations.

31. First, during an accountability audit, the investigation found that Defendants failed to maintain dispensing records for multiple controlled substances and/or failed to maintain records of receipt of controlled substances.

32. An accountability audit attempts to reconcile the physical counts from both the pharmacy's last biennial inventory and the date of the inspection with the pharmacy's on-hand *receipts* of drug distributions and *dispensing records*.

33. As described above, pharmacies are required to maintain receipts of drug distributions and accurate dispensing records under the CSA.

34. The accountability audit of the period between May 2, 2022, and December 6, 2022, revealed thousands of unaccounted-for opioids, including a shortage of hydrocodone pills.

35. Second, during the inspection, DEA discovered that Defendants sold certain scheduled listed chemical products, including products containing ephedrine, pseudoephedrine, and phenylpropanolamine, directly to customers. Despite selling these products, Defendants had failed to submit annual certifications to DEA that their employees had been trained on CSA and DEA laws involving the sales of those products from December 1, 2018, through December 6, 2023.

COUNT I
(Civil Penalties for Unlawful Dispensing of Controlled Substances)

36. The United States repeats and realleges Paragraphs 1 through 35 as if fully set forth herein.

37. The CSA and its implementing regulations prohibited Defendants from dispensing controlled substances in violation of their corresponding responsibility to only dispense controlled substances pursuant to a prescription issued for a legitimate medical purpose and in the usual course of professional practice.

38. Defendants dispensed controlled substances in violation of their

corresponding responsibility to only dispense controlled substances pursuant to a prescription issued for a legitimate medical purpose and in the usual course of professional practice, in violation of 21 U.S.C. §§ 829 and 842(a)(1), and 21 C.F.R. § 1306.04(a).

39. As a result of the foregoing, Defendants are liable for penalties of up to $78,312 for each violation proven at trial. 21 U.S.C. §§ 842(a)(1), 842(c)(1)(A); 28 C.F.R. § 85.5.

COUNT II
(Civil Penalties for Failing to Keep Records)

40. The United States repeats and realleges Paragraphs 1 through 39 as if fully set forth herein.

41. The CSA and its implementing regulations prohibited Defendants from violating the CSA's recordkeeping requirements.

42. Defendants violated these recordkeeping requirements by failing to maintain complete and accurate records of receipts of distributions of controlled substances and complete and accurate controlled substance dispensing records, in violation of 21 U.S.C. §§ 827(a)(3) and 842(a)(5), and 21 C.F.R. §§ 1305.17 and 1304.22(c).

43. As a result of the foregoing, Defendants are liable for penalties of up to $18,170 for each violation proven at trial. 21 U.S.C. §§ 842(a)(5), 842(c)(1)(B)(i); 28 C.F.R. § 85.5.

COUNT III
(Civil Penalties for Failing to Report)

44. The United States repeats and realleges Paragraphs 1 through 43 as if fully set forth herein.

45. The CSA and its implementing regulations prohibited Defendants from failing to make reports required under 21 U.S.C. § 830.

46. Defendants violated this prohibition by failing to report an annual certification of training for Pattie Drug's employees regarding compliance with the CSA's requirements for selling scheduled listed chemical products, in violation of 21 U.S.C. §§ 830(e)(vii) and 842(a)(10).

47. As a result of the foregoing, Defendants are liable for penalties of up to $18,170 for each violation proven at trial. 21 U.S.C. §§ 842(a)(10), 842(c)(1)(B)(i); 28 C.F.R. § 85.5.

COUNT IV
(Injunctive Relief)

48. The United States repeats and realleges Paragraphs 1 through 47 as if fully set forth herein.

49. As a result of the violations referred to in Counts I, II, and III, Defendants are subject to injunctive relief pursuant to 21 U.S.C. §§ 843(f) and 882(a).

PRAYER FOR RELIEF

WHEREFORE, the United States demands judgment in its favor and against Defendants as follows:

A. As to Counts I, II, and III, for a maximum statutory penalty in the amounts set forth above for each violation of the CSA proven at trial pursuant to 21 U.S.C. § 842;

B. As to Count IV, entry of an order:

1. Declaring that Defendants violated the CSA, specifically 21 U.S.C. §§ 842(a)(1), 842(a)(5), and 842(a)(10);
2. Permanently enjoining Defendant Pattie Drug from directly or indirectly administering, delivering, dispensing, or distributing any controlled substance as defined and identified in the CSA;
3. Directing Defendant Pattie Drug to surrender its existing certificate of registration as a retail pharmacy with DEA; and
4. Enjoining Defendant Krawczak from directly or indirectly administering, delivering, dispensing, or distributing any controlled substance in a pharmacy setting unless that pharmacy also employs another individual who serves as the pharmacist in charge of that pharmacy and Defendant Krawczak is working under the supervision of that pharmacist in charge.

C. For interest, attorneys' fees, and costs as allowed by law; and

D. For all such other and further relief as the Court may deem just and proper.

Dated: January 26, 2024

Respectfully submitted,

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